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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/747,004 | 12/21/2000 | Jing-Shan Hu | 3366.1 | 2941 |

7590 02/22/2006

| EXAMINER | |
|---|---|
| KIM, YOUNG J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1637 | |

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DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/747,004 | HU ET AL. | |
| | Examiner | Art Unit | |
| | Young J. Kim | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The present Office Action is responsive to the Amendment received on August 29, 2005.

### *Preliminary Remark*

Applicants' petition to revive an unintentionally abandoned application was Granted on December 8, 2005.

No claims were canceled in the Amendment received on August 29, 2005; claims 25-27 have been added.

Claims 1-27 are pending and are under prosecution therefore.

### *Specification*

The amendment to the specification, amending to update the U.S. Application Serial number from application previously identified only by the attorney docket number is acknowledged.

It is acknowledged that the application serial number correspond to the attorney docket number and hence, no new matter has been introduced by the amendment.

### *Claim Rejections - 35 USC § 112*

The rejection of claims 15 and 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, made in the Office Action mailed on February 10, 2005 is withdrawn in view of the Amendment.

### *Rejection, New Ground – Necessitated by Amendment*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the pool of mRNAs." There is insufficient antecedent basis for this limitation in the claim.[1] For the purpose of prosecution, with respect to its dependency on claim 14, it is assumed that RNAs are fluorescently labeled.

### *Claim Rejections - 35 USC § 102 - Maintained*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-6, 12, and 15-18 under 35 U.S.C. 102(b) as being anticipated by Irvine et al. (U.S. Patent No. 5,736,316, issued April 7, 1998), made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on August 29, 2005 have been fully considered but they are not found persuasive for the following reasons.

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[1] Claim 16 is a multiple dependent claim, depending from claims 13-15. Claim 14 makes the distinction between mRNA (claim 13) and RNA (of claim 14). Therefore, claim 16, when dependent on claim 14, would lack proper antecedent basis for the limitation, "the pool of mRNA." In addition, the art-accepted term for RNAs derived from cDNAs are, "cRNAs."

Applicants' arguments will be addressed in the same order they were presented (in the "Response to Arguments" section).

The Rejection:

Irvine et al. disclose a method of detecting a plurality of nucleic acid targets, said method comprising the steps of:

a) hybridizing a capture probe (or mediator), said capture probe comprising a first segment having a target nucleic acid sequence and a second segment having a nucleotide sequence substantially complementary to an oligonucleotide (or cipher probe) bound to a solid phase (column 2, lines 33-40);

b) detecting the hybridization of the target nucleic acid (column 3, line 6).

The number of capture probes employed by Irvine et al. is disclosed as being between 5-100 (column 5, lines 28-29).

Therefore, Irvine et al. anticipate claims 1, 3, 4, and 12.

The capture probe and the immobilized probe of Irvine is disclosed as being oligonucleotides (column 3, lines 65-67), anticipating claim 2.

The immobilized oligonucleotide probes (or cipher probes) are disclosed as comprising at least 15 bases. This fact is evidenced by the section of the specification which discloses that each capture probe contains, in addition to the sequence substantially complementary to HBV DNA, the following downstream sequence complementary to DNA bound to the solid phase, wherein the sequence comprises 20 bases (column 11, lines 41-45), anticipating claims 5 and 6.

The detection is achieved via fluorescent labeling (column 7, lines 1-6), anticipating claims 15 and 16

The immobilized oligonucleotides of Irvine et al. are disclosed as being immobilized on their 5' end (column 11, lines 66 to column 12, line 17), anticipating claims 17 and 18.

The cipher probe which is synthesized in the direction of 5'-3' direction via photo-directed synthesis (*i.e.,* product-by-process) is structurally in no way different from that of Irvine et al., and therefore, the immobilized oligonucleotides of Irvine et al. would meet the limitations.

Therefore, the invention as claimed is anticipated by Irvine et al.

Response to Arguments:

On page 9 of the Response, Applicants contend that the method disclosed by Irvine et al. is drawn to a sandwich hybridization assay for detecting a single analyte (i.e., HBV) using multiple oligonucleotides: a set of amplifier probe oligonucleotides (mediator nucleic acids), a set of capture probe oligonucleotides, an oligonucleotide bound to the solid surface (cipher probes).

Initially, this characterization is not entirely correct.

As specifically pointed out on page 4 of the Office Action mailed on February 10, 2005, what is considered as a "mediator probe" is not an amplifier probe, but a capture probe.

As instantly claimed, the mediator probe is characterized as having a first subsequence that is complementary to one of the target nucleic acids and a second subsequence that is complementary to one of the cipher probes (the surface immobilized probes).

Irvine et al., on column 4, lines 24-28, describes their "capture probe," as having, "a first binding sequence substantially complementary to the analyte (i.e., target nucleic acid) and a second binding sequence that is substantially complementary to nucleic acid bound to a solid support (i.e., cipher probes). Thus, it should be noted that the structure of the claimed "mediator probe" is fully met by the "capture probe" of Irvine et al.

With regard to the structural limitation imposed by the cipher probes, Irvine et al. clearly states that the capture probes have a second binding sequence that is complementary to the nucleic acid bound to a solid support, thereby meeting the structural limitation imposed by the term, "cipher probes."

The point of contention is whether or not Irvine et al. teaches or discloses the detection of at least 50 nucleic acids by hybridization with at least 50 mediator nucleic acids and at least 50 different cipher probes.

Taken the teachings of Irvine et al. as a whole, clearly anticipate this limitation for the following reasons.

Claim 5 of Irvine et al. patent recites a set of synthetic oligonucleotides useful as capture probes (which is the structural equivalent of the claimed mediator probe), wherein its dependent claim 7 (directly dependent on claim 5), clearly recites that the probe set comprises 5 to 100 **different** oligonucleotide probes.

Thus, when the disclosure of Irvine et al. is taken as a whole, the artisans clearly teach a method involving at least 50 mediator nucleic acids.

With regard to whether the artisans teach at least 50 different cipher probes, is clearly inferred by Irvine et al..

In claim 5, Irvine et al., in describing the capture probe (mediator probe), clearly recites that the capture probe comprises a first segment complementary to the target nucleic acid sequence; and a second segment complementary to the oligonucleotides bound to the solid phase.

Thus, when claim 7, which directly depends from claim 5 recites 5-100 *different* capture probes, different conveying that the capture probes have different sequences, which undoubtedly includes the first and the second segments of the capture probe, would necessarily require that the

immobilized oligonucleotides also match the number of the capture probes, thereby also having 5-100 different oligonucleotides comprising sequences which are complementary to the second segments of the 5-100 different capture probes.

Hence, when 5-100 different capture probes is employed in a detection assay, said capture probes comprising a first segment complementary to a target nucleic acid sequence, would necessarily be drawn to a method which detects at least 50 nucleic acids. Coupled with the fact that the artisans do not prohibit the use of different immobilized oligonucleotides, the teaching, when taken as a whole, would clearly render the claims anticipated.

The rejection is maintained therefore.

The rejection of claims 1-18 and 21-24 under 35 U.S.C. 102(e) as being anticipated by Felder et al. (U.S. Patent No. 6,232,066 B1, issued May 15, 2001, filed July 2, 1998, priority December 19, 1997), made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

Claims 25-27 are rejected and addressed herein, the rejection being **necessitated by Amendment** (newly submitted claims).

Applicants' arguments presented in the Amendment received on August 29, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments will be addressed in the same order they were presented (in the "Response to Arguments" section)..

The Rejection:

Felder et al. disclose a method of detecting a plurality of nucleic acids in high throughput fashion, wherein said method comprises the steps of:

a) hybridizing the sample with at least 50 different linkers (Figure 1), wherein said linker comprises a first subsequence that is complementary to a target nucleic acid sequence and a second subsequence that is complementary to an anchor probe that is immobilized on an array surface (Figures 1 and 2); and

b) detecting the target nucleic acids (column 3, lines 5-10).

The specification discloses that for each well of 96-well microplates, at least 36 different tests performed using an array of 36 anchor and linker pairs (column 2, lines 16-17), which would result in 36 x 96 = 3,456 different anchors and linkers, thereby meeting, "at least 50 different linkers" limitation.

The "linker" probe of Felder et al. is identical in structure to "mediator," and "anchor" of Felder et al. is identical in structure to "cipher probes" of the instant application, anticipating claims 1, 12, and 21-24.

The linkers and anchors of Felder et al. is disclosed as being oligonucleotides or nucleic acids (column 4, line 51), anticipating claim 2.

As evidenced by Figure 1, the anchor probes (or cipher probes) do not hybridize to the target nucleic acids as well as any nucleic acids of the sample, anticipating claims 3 and 4.

The anchor employed by Felder et al. is, in an embodiment, disclosed as being 25 bases in length (column 29, bottom), anticipating claims 5 and 6.

While Felder et al. state that "the size and physical spacing of the test regions are not limiting," an example of an area of a test region (*i.e.,* single well, for example) is disclosed as being 1 to 40 $mm^2$, wherein based on the each test region comprising at least 36 anchors, the array of Felder et al. would necessarily comprise over 3,600 probes per $cm^2$, anticipating claims 7 and 8.

The linker (or mediator) of Felder et al. is disclosed as comprising a first region specific for target nucleic acid, wherein said first region comprises about 8 to 50 bases, and preferably 18, 20, 22, or 25 bases (column 11, lines 59-63); and a second region specific for the anchor (or cipher probe), wherein said second region comprises about 8 to 50 bases, and preferably 15, 20, 25, or 30 bases (column 11, lines 37-40), anticipating claims 9-11.

The samples are disclosed as being pool of mRNAs, DNA, RNA, or cDNAs, etc. (column 4, lines 21-24), anticipating claims 13-15, wherein such mRNA, or RNA are amplified (column 16, lines 60-62), thus anticipating new claims 25-27.

The detection is disclosed as being conducted via fluorescent moiety (column 8, lines 57-61), anticipating claim 16.

With regard to claims 17 and 18, the anchor of Felder et al. would necessarily meet their limitations because the anchor of Felder et al. is disclosed as being immobilized at its 5' end. The cipher probe which is synthesized in the direction of 5'-3' direction via photo-directed synthesis (*i.e.,* product-by-process) is structurally in no way different from that of Felder et al., and therefore, the anchor of Felder et al. would meet the limitations. In addition, Felder et al. clearly states that oligonucleotide linkers can be situated on or within the surface of a test region by any of variety of conventional techniques, "including photolithographic or silkscreen chemical attachment, disposition by ink jet technology..." (column 13, lines 28-32).

Therefore, the invention as claimed is anticipated by Felder et al.

Response to Arguments:

On page 10 of the Response, Applicants contend that the anchors (structural equivalent of the claimed cipher probes) of Felder et al. are the same for all screening assays (i.e., in each well)

pointing to column 2, line 40, column 3, lines 27-32 and Figure 2) and each well is therefore, specific for as many as 36 different targets (column 2, lines 42-43).

This argument is not found persuasive because Felder et al., on column 7, lines 42-57, in discussing a test region, discloses the below:

"The number of anchors in a test region can be at least two, preferably between about 8 to 900 (more or less being included), more preferably between about 30 and about 100 (e.g., about 64). In a most preferred embodiment, each anchor in a test region has a different specificity from every other in the array."

Hence the artisans, in their most preferred embodiment of the invention considers that each anchor have a different specificity from every other. A test region comprising 8 to 900; or 30 to100 anchors in view of this teaching would clearly mean that each anchor of the 8 to 900; or 30 to 100 anchors in the test region also have different specificity from each other. When the anchors have different specificity, in the case of nucleic acid sequence, of course, would mean that their sequences are different. Felder et al. have already demonstrated their contemplation of using oligonucleotides as anchor sequences (see for example, column 6, lines 64-67, in the phrase, "[i]n a preferred embodiment, the anchor is a nucleic acid, which can be of any length (e.g., oligonucleotide) or type (e.g., DNA, RNA, PNA, or a PCR product...."). This interpretation is consistent with that which is being claimed by Felder et al. in claim 1, wherein the claim recites:

"a surface comprising multiple spatially discrete regions, at least two of which are substantially identical, each region comprising ii) at least two different anchors (a cipher probe equivalent) each in association with iii) a bifunctional linker (a mediator probe equivalent).

Clearly, the artisan in the relevant field, when reading the below disclosure:

"The number of anchors in a test region can be at least two, preferably between about 8 to 900 (more or less being included), more preferably between about 30 and about 100 (e.g., about 64). In a most preferred embodiment, each anchor in a test region has a different specificity from every other in the array";

with the below disclosure:

"a surface comprising multiple spatially discrete regions, at least two of which are substantially identical, each region comprising ii) at least two different anchors (a cipher probe equivalent) each in association with iii) a bifunctional linker (a mediator probe equivalent)";

would conclude that the use of at least 50 different anchor probes was clearly taught by Felder et al.

Therefore, Applicants' arguments are not found persuasive and the rejection is maintained.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 19 and 20 under 35 U.S.C. 103(a) as being unpatentable over Felder et al. (U.S. Patent No. 6,232,066 B1, issued May 15, 2001, filed July 2, 1998, priority December 19, 1997) in view of Southern et al. (U.S. Patent No. 6,150,095, issued November 21, 2000, 102(e) date October 6, 1997), made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on August 29, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments will be addressed in the same order they were presented (in the "Response to Arguments" section).

The Rejection:

The teachings of Felder et al. have been discussed above.

Felder et al. do not explicitly state that the anchors be synthesized in the 3'-5' direction on the substrate.

Southern et al. disclose a well-known technique of synthesizing probes on a substrate in the 5'-3' direction or 3'-5' direction (column 3, lines 5-6), wherein the artisans state:

"The probe may be tethered to a support, preferably by a covalent linkage and preferably through a 5' or 3' terminal nucleotide residue."

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Felder et al. with the well-known knowledge of probe immobilization, as evidenced by Southern et al. to arrive at the claimed invention.

MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success. Given that the only difference of the claims and that of Felder et al. is the direction in which the probes are immobilized, based on the prior art knowledge (as evidenced by Southern et al.), one of ordinary skill in the art would have had a reasonable expectation of success at immobilizing the anchor probes of Felder et al. at their 3' termini to arrive at the claimed invention.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Response to Arguments:

On page 11 of the Applicants' Response, Applicants traverse this rejection, but all of the arguments were drawn to the propriety of the primary reference, Felder et al.

As discussed above, Felder et al. serves as a proper primary reference, teaching all of the limitations which Applicants assert missing. Since no new arguments have been presented in the Response, the rejection is maintained for the reasons of record.

The rejection of claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Irvine et al. (U.S. Patent No. 5,736,316, issued April 7, 1998) in view of Southern et al. (U.S. Patent No. 6,150,095, issued November 21, 2000, 102(e) date October 6, 1997[1]), made in the Office Action mailed on February 10, 2005 is maintained for the reasons of record.

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Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Response to Arguments:

On page 11 of the Applicants' Response, Applicants traverse this rejection, but all of the arguments were drawn to the propriety of the primary reference, Irvine et al.

As discussed above, Irvine et al. serves as a proper primary reference, teaching all of the limitations which Applicants assert missing. Since no new arguments have been presented in the Response, the rejection is maintained for the reasons of record.

***Double Patenting – Duplicate claims, Necessitated by Amendment***

Applicant is advised that should claim 16 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Note that claim 16 is a multiple dependent claim, depending from claims 13-15. Claim 16 (depending from claim 13) already recites that the pool of mRNAs comprises fluorescently labeled nucleic acids. Hence, claim 26, which also

depends from claim 13 reciting the same limitation, "wherein the pool of mRNAs comprises fluorescently labeled nucleic acids," are exact duplicate and thus would be redundant.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Conclusion*

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

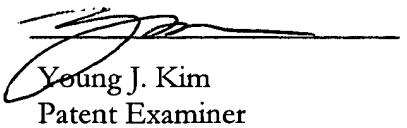
### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is

on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
2/21/2006

YOUNG J. KIM
PATENT EXAMINER

yjk